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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KOSTELNIK, SUMMER

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,681	Applicant(s) KOGA ET AL.	
	Examiner SUMMER L. KOSTELNIK	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This action is in response to Amendments filed December 29, 2010. Currently claims 9-16 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson, Pub. No. US 2002/0133175 A1 in view of Nemee et al., Pub. No. US 2004/0153083 A1 (hereinafter Nemee) in view of in view of Mack et al., Pub. No. US 2004/0267260 A1 (hereinafter Mack) in further view of Baumrind et al., Pat. No. US 6,621,491 (hereinafter Baumrind).

Regarding claim 9, Carson discloses a total knee joint replacing operation assisting terminal, constituted by a computer configured to assist a total knee joint replacing operation by performing a planning assistance function and an intraoperative assistance function (paragraph [0009]); wherein the planning assistance function is used before an intervention on a patient and the intraoperative function is used during the intervention on a patient (paragraph [0009]), whereby the terminal is configured to assist the total knee joint replacing operation performed with aid of a bone cutting positioning jig indicating a bone cutting direction by the intraoperative assistance function (paragraph [0100]); and an intra-medullary rod fixed to one end of the bone cutting positioning jig (paragraph [0100]); wherein the planning assistance function includes: acquiring a load shaft of a patient's foot from 3-dimensional radiographic image data and storing

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computer model data (paragraph [0075]), on the intra-medullary rod to be inserted into a medullary cavity (paragraph [0075]), in a database; wherein the intraoperative assistance function includes: acquiring, from the database, the computer model data on the intra-medullary rod to be inserted (paragraph [0075]); reading the computer model data, acquired from the database, on the intra-medullary rod to be inserted (paragraph [0075]); acquiring by C-arm fluoroscopic apparatus (paragraph [0075]), radiographic image data of the intra-medullary rod inserted into a tibia of the patient; acquiring, on the radiographic image data obtained by the fluoroscopic apparatus (paragraph [0075]), rotational position information on the intra-medullary rod in a medullary cavity of the patient based on the position of the intersection of the pair of wires of the intra-medullary rod (paragraph [0075]); and determining resected bone surface using the intra-medullary rod as a reference anatomical axis (paragraph [0096]); and wherein an anterior articular surface of the femur is determined perpendicularly to the load shaft of the patient from an angle with the femoral load shaft determined using the planning assistance function before the intervention (paragraph [0082]), and a bone surface to be resected is determined (paragraph [0096]).

However, Carson does not disclose wherein the bone cutting positioning jig comprises a bone cutting direction indicator having a base, a universal joint being movably and rotatably supported around three axes to the base of the bone cutting direction indicator through a ball joint and having a direction indicating jig or wherein the intra-medullary rod comprises a cylindrical body made of an X-ray transmitting material fixed at a central portion between a pair of bone ends of the intra-medullary rod, a plurality of wires, which are made of a material that does not transmit x-ray and are deposited at regular intervals along a surface of the cylindrical

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body in the circumferential direction, being extended in an axial direction in a spiral shape; wherein an intersection of each of the wires having a marker indicator functions providing rotational position information; wherein each of the wires is made in a way that a starting end and a terminating end of the cylindrical body are connected by the shortest distance along the outer surface thereof.

Nemec discloses an alignment guide for positioning an instrument to facilitate resecting the bone comprising a base (30), a universal joint movably and rotably supported around three axes to the base of the bone cutting direction indicator through a ball joint (20). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the Carson system to include the jig taught by Nemec in order to allow for greater freedom of positioning which increases efficiency during surgery.

Carson in view of Nemec substantially disclose the invention as claimed, including an intra-medullary rod, but do not disclose wherein the intra-medullary rod comprises a cylindrical body made of an X-ray transmitting material fixed at a central portion between a pair of bone ends of the intra-medullary rod, a plurality of wires, which are made of a material that does not transmit x-ray and are deposited at regular intervals along a surface of the cylindrical body in the circumferential direction, being extended in an axial direction in a spiral shape; wherein an intersection of each of the wires having a marker indicator functions providing rotational position information; wherein each of the wires is made in a way that a starting end and a terminating end of the cylindrical body are connected by the shortest distance along the outer surface thereof.

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However, Mack discloses a rod having a cylindrical shape (Figs. 4-9), including a plurality of wires (Figs. 4-9) which are made of a material that does not transmit x-ray (paragraph [0006]) and are deposited at regular intervals along a surface of the cylindrical body in the circumferential direction (Figs. 4-9), being extended in an axial direction in a spiral shape (Figs. 4-9); wherein an intersection of each of the wires having a marker indicator functions providing rotational position information (since the wires do not transmit x-ray the crossing of the wires serves as a marker indicating rotational position); wherein each of the wires is made in a way that a starting end and a terminating end of the cylindrical body are connected by the shortest distance along the outer surface thereof (Figs. 4-9). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the Carson in view of Nemec device such that the rod was structured as described by Mack in order to locally modify the properties of the rod (paragraph [0006]).

Further, Carson in view of Nemec in view of Mack does not disclose where the rod is made of a material that transmits x-rays; however, Baumrind discloses using radiolucent rods in systems and methods for integrating 3D diagnostic data (col. 7, lines 20-34). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the Carson in view of Nemec in view of Mack device such that the intra-medullary rod is made of a radiolucent material as taught by Baumrind in order to provide a less obstructed view of the implant.

Regarding claim 10, Carson discloses that the planning assistance function further includes performing a 3-dimensional simulation for mounting an artificial knee implant based on the 3-dimensional radiographic image data (paragraph [0019]).

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Regarding claim 11, Carson discloses that the planning assistance function further includes determining a kind of artificial knee implant to be used (paragraph [0011] and paragraph [0110]).

Regarding claim 12, Carson discloses that the planning assistance function further includes determining a setting position of the artificial knee implant (paragraph [0019]).

Regarding claim 13, Carson discloses that the planning assistance function further includes superimposing the 3-d radiographic image data with the setting position of the artificial knee implant (paragraph [0098]).

Regarding claim 14, Carson discloses that the intraoperative assistance function further includes superimposing the computer model data on the intra-medullary rod to be inserted on the radiographic image data acquired during the intraoperative assistance function (paragraph [0098]).

Regarding claim 15, Carson discloses that the intraoperative assistance function further includes resecting a bone surface using the bone cutting positioning jig and the determined resected bone surface (paragraph [0096]).

Regarding claim 16, Carson discloses that the radiographic image data is a fluoroscopic image (paragraph [0010]).

Response to Arguments

Applicant's arguments with respect to claim 9 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SUMMER L. KOSTELNIK** whose telephone number is (571)270-5339. The examiner can normally be reached on M-F 7:30-5:00, 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. L. K./

Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733